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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,192	06/12/2001	Michael G. Walker	PB-0009-1 CIP	7368

7590 05/13/2002

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EXAMINER
GUNTER, DAVID R

ART UNIT	PAPER NUMBER
1634	6

DATE MAILED: 05/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/880,192	Applicant(s) WALKER ET AL.
	Examiner David Gunter	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 and 13-14, drawn to a composition comprising a plurality of polynucleotides; an isolated polynucleotide comprising a nucleic acid sequence selected from SEQ ID NOs: 1-48 and complements thereof; a composition comprising a polynucleotide selected from SEQ ID NOs: 1-48 and a labeling moiety; a vector comprising a polynucleotide selected from SEQ ID No. 1-48, all classified in class 536, subclass 23.1; and to a host cell comprising a vector comprising a polynucleotide selected from SEQ ID No. 1-48, classified in class 424, subclass 93.21

II. Claims 4-6 drawn to a method of using a polynucleotide to screen a plurality of molecules, classified in class 436, subclass 501.

III. Claims 7 and 8, drawn to a method of purifying a ligand, classified in class 436, subclass 501.

IV. Claims 9-12 drawn to a method for using a polynucleotide to detect gene expression, classified in class 436, subclass 501.

V. Claim 15, drawn to a method to use a host cell to produce protein, classified in class 435, subclass 69.1.

VI. Claim 16 and 17, drawn to a purified protein comprising an amino acid sequence selected from SEQ ID No: 49-62, classified in class 530, subclass 300 or 350 (depending on the length of the individual sequence), and to a composition of a

purified protein and a pharmaceutical carrier or labeling moiety, classified in class 514, subclass 2

VII. Claims 18-19, drawn to a method of using protein to screen for ligands, classified in class 436, subclass 501.

VIII. Claim 20, drawn to a method of using protein to prepare and purify antibodies, classified in class 436, subclass 547.

1. Inventions II-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention II describes the use of a polynucleotide to screen a plurality of potential ligands. These potential ligands may include DNA molecules, RNA molecules, peptide nucleic acids, mimetics, and proteins as recited in claim 6. Invention II describes only a method for binding a polynucleotide to the potential ligands and detecting binding with the objective of identifying ligands. Invention III adds the additional steps (modes of operation) of recovering the bound polynucleotide and separating the ligand from the bound polynucleotide to obtain purified ligand (effect). Invention IV describes a method of using a polynucleotide to detect gene expression. Invention IV differs from invention II in that the potential ligand used in invention IV is inherently limited to nucleic acids extracted from a tissue or cultured cell if gene expression is to be assessed. The differences between invention II and IV in terms of the material to be screened and the type of data generated (effect) require a substantially different technique (mode of operation) for carrying out each of the processes. Invention V describes a method to use a host cell to produce protein.

Production of protein is a substantially different effect and requires a substantially different mode of operation that those associated with Inventions II-IV. The differences in modes of operation and the effects of inventions II-V cause them to be distinct inventions.

2. Invention I is related to inventions II-V as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes described by inventions II-V are distinct processes each with a unique mode of operation and effect as described above. The product (plurality of polynucleotides and transfected host cell) described in claim I can be used for any of the distinct processes described by inventions II-V. For this reason restriction for the purposes of examination is considered proper.

3. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Nucleotide sequences encoding proteins are structurally and functionally distinct chemical compounds from their encoded proteins and so are unrelated to the protein. The nucleotide and the protein encoded are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121.

4. Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Invention II uses a polynucleotide to screen a plurality of molecules to identify potential ligands while Invention VII uses a protein to screen a plurality of molecules to identify potential ligands. As described above, nucleotide sequences encoding proteins are structurally and functionally distinct chemical compounds from their encoded proteins and so are unrelated to the protein. As a result, Invention II and VII have substantially different modes of operation, functions, and effects, and so restriction for the purposes of examination is deemed proper.

5. Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product (the purified protein) can be made using a variety of different methods including solid-state synthesis and *in vitro* peptide synthesis that are distinct from the claimed process of invention V.

6. Invention VI is related to inventions VII and VIII as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case inventions VII and VIII are distinct and unrelated processes. Invention VII describes a method of using a purified protein (invention VI) to screen a plurality of molecules to identify ligands. These potential ligands may include DNA molecules, RNA molecules, peptide nucleic acids, mimetics, proteins, agonists, antagonists, and antibodies as described in claim 19. Invention VIII describes a method of using a purified protein (invention VI) to prepare and purify antibodies by injecting the purified protein into an animal, isolating the antibodies produces, then affinity-purifying the antibodies using the original peptide antigen. These two processes of invention VII and VIII are considered to be patentably distinct based on their differences in mode of operation and effects. Because the purified peptide (invention VI) can be used in either of these unrelated processes, it is considered to be a distinct invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David R. Gunter whose telephone number is (703) 308-1701. The examiner can normally be reached on 9:00 - 5:00 M - F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-9212 for regular communications and (703) 308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

David R. Gunter, DVM, PhD
May 6, 2002